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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,137	NGYUYEN MAI	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *8-10 and 12-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-7 and 11) in the response filed 8/16/03 is acknowledged. Claims 8-10 and 12-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 8/16/03.

Claim Objections

Claim 1 is objected to because of the following informalities: it has two periods at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following are three different grounds of rejection under 35 U.S.C. 112 1st paragraph for lack of written description directed to the same set of claims. The different grounds of rejection were necessitated by the multiple alternatives presented by the Markush group of different nucleic acids recited in claim 1.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of the claims is directed to an isolated nucleic acid selected from the group consisting of: (i) a nucleic acid that specifically hybridizes to a human EG-1 cDNA (coding region of SEQ ID NO: 1) under stringent conditions, (ii) a nucleic acid encodes a human EG-1 polypeptide (SEQ ID NO: 2), (iii) a nucleic acid that has the same sequence as a nucleic acid amplified from an endothelial cell mRNA template using specific primers, (iv) a DNA encoding an mRNA that can be reverse transcribed to produce a human EG-1 cDNA. Each of these members of the Markush group of claim 1 read on genomic DNAs encoding a human EG-1 polypeptide. The instant specification indicates that the genomic sequences for the human EG-1 gene are known in that it describes in general terms the presence of exons and introns. The genomic sequences associated with the EG-1 gene (e.g. promoter, terminator and intervening sequences) are not in fact described in the specification. There is no basis for the skilled artisan to envision those genomic embodiments encompassed by the rejected claims. Therefore, the skilled artisan would have recognized applicant was not in possession of the claimed invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, part (iii), recites a limitation that the nucleic acid of the invention comprises a nucleic acid sequence "that has the same sequence as a nucleic acid amplified from an endothelial cell mRNA template" using specific PCR primers. The claim encompasses any variant sequence of that disclosed by the instant specification (SEQ ID NO: 1), as well as any intervening sequences between the primers that may be amplified by the recited primers. In addition, there is no description of the stringency of the hybridization conditions used in the amplification such that one cannot predict what other sequences might be amplifiable by the cited primer sequences. Therefore, there is no basis provided by the instant specification for the skilled artisan to envision a sufficient number of specific amplification products that are embraced by the rejected claims to describe the broadly claimed genus.

The prior art does not appear to offset the deficiencies of the instant application with regard to the specific primers and amplification of EG-1 sequences, as such methods appear to be novel in the art. For the reasons outlined above, the skilled artisan would not have been able to envision a sufficient number of specific amplification products that are embraced by the rejected claims to describe the broadly claimed genus. The skilled artisan would reasonably have concluded applicant was not in possession of the claimed invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, part (iv), is directed to an unidentified pair of primers capable of "specifically" amplifying an endothelial cell mRNA template encoding a human EG-1 polypeptide. The metes and bounds of the term "a human EG-1 polypeptide" are unclear (see the 112 2nd rejection below). The term can be read broadly to encompass any polypeptide within SEQ ID NO: 2. The protein described by SEQ ID NO: 2 is 178 amino acids in length and encoded by a disclosed cDNA of ~1.2 kb in length. The term "specifically amplifying" is not defined in the specification and the amplification conditions are not defined in the claims. The specification does not describe a sufficient number of specific pairs of primers to describe the broadly claimed genus of such primer pairs and which must also satisfy the broadly recited functional limitations of the claims. Therefore, one of skill in the art would have reasonably concluded applicants were not in possession of the claimed nucleic acid primers.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...specifically hybridizing to a human EG-1 cDNA or a fragment thereof under stringent hybridization conditions..." are unclear. First, the specification provides multiple sources and definitions as to what constitutes "stringent hybridization" conditions. Which set of conditions is applicable in

this case? Second, the term "specifically hybridizing" is not clearly defined in the specification. How "specific" does the hybridization have to be in order to satisfy this limitation?

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...of sufficient length that said nucleic acid can uniquely indicate the presence or absence of a human EG-1 total genomic DNA pool, a total cDNA pool or a total mRNA pool sample from an endothelial..." are unclear. It is unclear what is intended by this phrase because the concept of an EG-1 total DNA, cDNA or mRNA pool is not clearly defined in the specification. It appears the specification may be intended to mean that the nucleic acid can be used as a probe to indicate the absence or presence of EG-1 coding sequences in a total gDNA, cDNA or mRNA pool from a host cell.

Claim 1, part (ii), recites "the words "a" human EG-1 polypeptide followed by the parenthetical use of the words "SEQ ID NO: 2". This makes it unclear as to whether the phrase encompasses only the full length sequence described by SEQ ID NO: 2, or whether it also encompasses fragments of SEQ ID NO: 2.

Claim 1 is vague and indefinite in that the metes and bounds of the parenthetical phrase "coding region of SEQ ID NO: 1" are unclear. Since the phrase is parenthetical and follows the words "a human EG-1 cDNA", it is unclear if the limitation is specifically limited to the coding region of SEQ ID NO: 1, or if the parenthetical phrase is merely an example of a human EG-1 cDNA.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...a pair of primers that....specifically amplifies a nucleic acid encoding a human EG-1 polypeptide (SEQ ID NO: 2)..." are unclear. First, it is unclear what is intended by the term "specifically

amplifies". How "specific" does the amplification have to be in order to satisfy this limitation? Second, the words "a" human EG-1 polypeptide followed by the parenthetical use of the words "SEQ ID NO: 2" make it unclear as to whether the phrase encompasses only the full length sequence described by SEQ ID NO: 2, or whether it also encompasses fragments of SEQ ID NO: 2.

Similarly, claim 11 recites the limitation of "an EG-1 polypeptide". Does this term refer only to the full-length protein or does it also encompass fragments of the full-length protein?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitt et al (WO 99/47655 A; see the entire document) or Schmitt et al (WO 99/53040 A; see the entire document).

Each of the Schmitt et al applications describes human mRNAs, cDNAs and genomic sequences that are obtained from or present in ovarian tumor tissue or normal breast tissue. Specifically, each of the applications teach nucleic acid sequences that encode a protein comprising a polypeptide sequence having 100% identity with SEQ ID NO: 2 (e.g. SEQ ID NO: 259 from WO 99/53040; SEQ ID NO: 65 from WO 99/47655; see the attached sequence search results for 10-029-137-2.rge). The nucleic acid sequences taught in these applications have

extensive homology with SEQ ID NO: 1. For example, SEQ ID NO: 65 of WO 99/47655 has 82% similarity to SEQ ID NO: 1, with 99.9% identity across nucleotides 1-1056 of SEQ ID NO:1 (see the attached reports for 10-029-137-1.rge). SEQ ID NO: 259 from application WO 99/53040 has 82% similarity to SEQ ID NO: 1, with 99.9% identity across nucleotides 1-1056 of SEQ ID NO:1 (see the attached reports for 10-029-137-1.rge). Thus, the Schmitt et al applications teach each of the limitations for claim 1, parts (i-v).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over (WO 99/47655 A; see the entire document) or Schmitt et al (WO 99/53040 A; see the entire document).

The teachings of the Schmitt et al applications are described above, and applied as before to claims 1-5 and 11, except:

Schmitt et al do not appear to explicitly teach the use of a labeled nucleic acid encompassed by claim 1.

It would have been prima facie obvious to one of ordinary skill in the art to use a labeled probed corresponding the EG-1 nucleic acids described by Schmitt et al (i.e. SEQ ID NO: 259 from WO 99/53040; SEQ ID NO: 65 from WO 99/47655) to clone the cDNA or genomic DNA

sequences from libraries comprising cDNA and/or gDNAs. Alternatively, it would have been obvious to use such labeled probes to identify homologs of the genes identified by Schmitt et al. One would have been motivated to do so in order to clone and express the polypeptides identified by Schmitt et al as being expressed in breast and/or ovarian tumor tissue, or genes encoding homologs thereof. Absent any evidence to the contrary, there would have been a reasonable expectation of success labeling and using nucleic acid probes derived from the nucleic acid sequences taught by Schmitt et al and which are embraced by the rejected claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

Ggl

GERRY LEFFERS
PRIMARY EXAMINER